K010413

AUG - 2 2001

Compliance Systems +, LLC

458 S. Random Road
Bailey, CO 80421
Phone/fax: (303) 838-8619

SUMMARY OF 510(K) SAFETY AND EFFECTIVENESS
Minolta PULSOX-3 and PULSOX-3I

February 6, 2001

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The Minolta PULSOX-3Si, PULSOX-3iA and PULSOX-3Li are similar in function, design and construction to other products which were in the market place prior to May 28, 1976. The Minolta PULSOX-3Si, PULSOX-3iA and PULSOX-3Li are also similar to several other products currently being marketed in the United States including the legally marketed predicate device and a substantial equivalence claim made. The predicate devices are the Minolta PULSOX-3 and PULSOX-3i. The predicate device is a legally marketed Class II post-amendment device, **K-984570** currently manufactured by Minolta Co., Ltd., Osaka, Japan.

The Minolta PULSOX-3Si, PULSOX-3iA and PULSOX-3Li are the devices for determination of saturation of hemoglobin (SpO_2) non-invasively from light signals of two wavelengths transmitted through from tissues of patients who have pulmonary disease, pulmonary dysfunction or who need sleep study. SpO_2 is, as defined in 1.3.14 of ISO 9919:1992, percent of hemoglobin saturation with oxygen measured by a pulse oximeter and displayed as a percentage. The measurement principle depends on a changing signal caused by the pulsatile nature of blood flow.

Performance indicates that the Minolta PULSOX-3Si, PULSOX-3iA and PULSOX-3Li are equivalent to the Minolta PULSOX-3 and PULSOX-3i. The testing results are also in compliance with those in published literature for pulse oximeters. The testing conducted demonstrates that the Minolta PULSOX-3Si, PULSOX-3iA and PULSOX-3Li are safe and effective.

Nanci Dexter
Owner, Compliance Systems +, LLC

2001 FEB 06
Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Ms. Nanci Dexter
Minolta, Co., Ltd.
c/o Compliance Systems
458 S. Random Road
Bailey, CO 80421

Re: K010413
Minolta PULSOX-3Si, PULSOX-3iA, PULSOX-3Li
Regulation Number: 868.2700
Regulatory Class: II (two)
Product Code: 74 DQA
Dated: May 16, 2001
Received: May 17, 2001

Dear Ms. Dexter:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this

response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for

James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K010413

Device Name: PULSOX-3Si, PULSOX-3iA and PULSOX-3Li

Indications for Use:

The Minolta PULSOX-3Si, PULSOX-3iA and PULSOX-3Li are the devices for determination of saturation of hemoglobin (SpO_2) non-invasively from light signals of two wavelengths transmitted through from tissues of patients who have pulmonary disease, pulmonary dysfunction or who need sleep study.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

Division of Cardiovascular & Respiratory Devices
510(k) Number K010413